DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
D1428B

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

February 12, 1998

WARNING LETTER
CHI-15-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Franklin B. Zorn, President
Omron Healthcare
300 Lakeview Parkway
Vernon Hills, IL 60061

Dear Mr. Zorn:

Between August 6 and October 27, 1997, we notified you of our intent to inspect various shipments of medical devices offered for import into the United States by your firm from August 5 to October 26, 1997. The shipments were made under entry numbers[ ] [ ] and [ ] These shipments were not held intact and were moved to the importer's premises and distributed without an FDA release. This is a violation of Title 21, Code of Federal Regulations, Section 1.90 (copy enclosed), which requires the importer to hold an entry intact pending receipt of a "May Proceed" or "Release" Notice from FDA.

Failure to prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to prevent future violations. Your written reply should be addressed to this office, attention Robert A. Sittig, Compliance Officer.

Sincerely,

Raymond V. Mlecko
District Director

Enclosure